REMARKS

Claims 18, 35 and 53-85 were pending. With the cancellation of claim 64, claims 18, 35, 53-63 and 65-85 are pending. The amendment to claim 62 is supported by the specification as filed at page 9, lines 13-15 (i.e., paragraph [0054] in page 3 of the published application, US 2004/0097528 A1).

Claims Allowed

The applicants would like to thank Examiner Berch for holding that claims 35 and 58 were allowed and that claims 54 and 55 recite allowable subject matter. The Office Action asserts that claim 54 and 55 are objected to only as being dependent on a rejected base claim but would be allowable if rewritten in independent form to include all of the features recited in any base and intervening claims.

Claim Rejections -- 35 U.S.C. 112, First Paragraph

Claims 59-64, 66-69 and 74-77 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement.

With regard to claims 74-76, the Office Action states that pharmaceutically acceptable compositions cannot include unsafe organic solvents and that methanol is considered a toxin. Applicants disagree because whether methanol would cause any adverse health effects depends on the dose of the methanol administered to an individual. However, in order to advance prosecution, without acquescence with the Examiner's position, methanol solvate has been deleted from the formulation claims 74 and 75, rendering the rejection moot Thus, withdrawal of the rejection of claims 74-76 are respectfully requested.

With regard to claim 62, the Office Action states that the specification is somehow contradicted by Experiment 6 of the Declaration submitted on April 23, 2009. Claim 62 is amended to recite a process for preparing crystalline solid famciclovir characterized by a XRD pattern with peaks at 15.5 and 15.9 ± 0.2 deg. 2θ, comprising the steps of: a) heating famciclovir monohydrate to about 60° C to about 70° C; and b) isolating the crystalline solid famciclovir characterized by a XRD pattern with peaks at 15.5 and 15.9 ± 0.2 deg. 2θ. Experiment 6 demonstrated that experimental reproduction of the recrystallization procedure of Brand et al. (1999), *Tetrahedron* 55:5239-5252, in particular the recrystallization of famciclovir from a water:acetone (50:50, v/v) mixture in the paragraph bridging pages 5250 and 5251, yielded famciclovir monohydrate, not famciclovir, from the use of aqueous acetone. The Office Action alleges that because in Experiment 6 famciclovir monohydrate was heated at 45° C and Form I did not result, that the specification is not enabling for Form I produced according to the process recited in claim 62. Experiment 6, however, only shows

that Form I did not result according to the process described in Brand et al. These results do not contradict that Form I is formed according to the process recited in the amended claim 62 when the monohydrate is heated at about 60° C to about 70° C and there is no evidence that heating the monohydrate at about 60° C to about 70° C would not result in Form I. Thus, reconsideration and withdrawal of the rejection of claim 62 are respectfully requested.

With regard to claims 59-61, 66-69 and 72-77, the Office Action argues that ethanol solvate cannot be enabled. The Office Action states that the disclosure in the Applicants' specification of Form III as both the ethanol and methanol solvates with the same physiochemical properties and the same XRD pattern cannot be taken correct on its face allegedly because, among other reasons, methanol is a toxin and ethanol is not; ethanol is a desiccant and methanol is not. Applicants contend that the ethanol solvate is enabled. Just because methanol and ethanol have differences in toxicity and desiccant properties does not necessarily prevent the methanol solvate and ethanol solvate of famciclovir to have the same physicochemical properties and XRD pattern. The reason is that as solvates, the methanol molecules or ethanol molecules are trapped in the crystal lattice of famciclovir crystalline Form III. The toxicity properties and desiccant properties of methanol and ethanol have no bearing on how the solvent molecules are trapped in the crystal lattice of famciclovir crystalline form. As long as the methanol molecules or ethanol molecules are trapped in substantially the same crystal lattice of famciclovir, the methanol solvate and the ethanol solvate can have the substantially same physicochemical properties such as XRD pattern as disclosed in the specification.

The Office Action further argues that the specification does not teach how to make ethanol solvate. Applicants disagree. Applicants contend that based on the disclosure of the specification as a whole, one of ordinary skill in the art would understand how to make an ethanol solvate using ethanol as a solvent, as such task is well within the capacity of one of ordinary skill in the art. The specification presents evidence that the inventors did prepare ethanol solvate of famciclovir as shown in Examples 8 and 9 in page 13 of the specification. In Example 8, a mixture of crystalline famciclovir Form III and famciclovir Form I was prepared after triturating a 3 gram mixture of crystalline famciclovir Forms I and II in 20 drops of ethanol at room temperature for 5 days. Example 9 shows that a mixture of crystalline famciclovir Form III and monohydrate was prepared by stirring a 3 gram mixture of crystalline famciclovir Forms I and II in 30 ml of ethanol at room temperature. Since ethanol was used in both Examples 8 and 9, without any methanol present, the Form III produced in Examples 8 and 9 had to be famciclovir ethanol solvate, not famciclovir methanol solvate. Thus, Examples 8 and 9 show that famciclovir ethanol solvate was produced in the invention. The two sentences in page 12, lines 26-30, of the specification, as noted by the Office Action, are not contradictory because a person skilled in the art would interpret the two sentences in view of Examples 8 and 9. Therefore, applicants contend that

the person would be able to prepare the famciclovir ethanol solvate based on the disclosures in the specification. Accordingly, reconsideration and withdrawal of the rejection of claims 59-61, 66-69 and 72-77 are respectfully requested.

Claims 18, 53, 56, 57, 60-72 and 78-85 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action argues that the forms recited in these claims are defined by only two peaks and that two peaks are allegedly not enough to define a particular crystalline form. MPEP 2163(I) instructs "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. In at least Figs. 1-3 and page 7, line 25 – page 8, line 9, the Applicants disclose the complete XRD patterns for the claimed forms of famciclovir. In view of Figs. 1-3, the person skilled in the art would have understood that the two PXRD peaks recited in the claims are characteristic peaks sufficient to distinguish one known crystalline form of famciclovir from other known crystalline forms of famciclovir. Thus, the specification clearly describes the invention in sufficient detail so as to comply with the written description requirement. For at least this reason, reconsideration and withdrawal of the rejection of claims 18, 53, 56, 57, 60-72 and 78-85 are respectfully requested.

Claim Rejections -- 35 U.S.C. 112, Second Paragraph

Claims 18, 53, 56, 57, 60-72 and 78-85 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite The Office Action asserts that allegedly because Forms I and II are described in the specification as sharing XRD peaks at 17.0 and 25.6 that it is unclear which forms Applicants are claiming. Applicants disagree. The independent claims drawn to each form of famciclovir are defined according to two peaks unique to that form. Certain claims depending from the independent claims further define additional XRD peaks relating to those forms. The Applicant notes that the shared peaks cited by the Office Action, 17.0 and 25.6, are not recited in the pending claims. For at least these reasons, the Applicants respectfully submit that the pending claims clearly recite the specific form of famciclovir to which they are drawn and, as such, are definite. Reconsideration and withdrawal of the rejection of claims 18, 53, 56, 57, 60-72 and 78-85 are respectfully requested.

Conclusion

With the above reasoning, Applicants submit that the application is in a condition for allowance. The Examiner is urged to contact the undersigned by phone if there remains any minor issues.

In the event that the filing of this paper is deemed not timely, applicants petition for an appropriate extension of time. The petition fee and any other fees that may be required in relation to this paper can be charged to Deposit Account No. 11-0600 referencing Attorney Docket No. 01662/60903.

Respectfully submitted,

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